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Mary Wilkes Eubanks

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Mary Wilkes Eubanks
8 Pilton Place
Durham, NC 27705

EXAMINER

ROBINSON, KEITH O NEAL

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,255

Applicant(s)

EUBANKS, MARY WILKES

Examiner

Keith O. Robinson, Ph.D.

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-43 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 23-43 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____.
 4) ☐ Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) ☐ Notice of Informal Patent Application
 6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action, mailed August 11, 2005.
2. The cancellation of claims 1-22 and the addition of new claims 23-43, filed August 16, 2006, have been received and entered in full. However, Applicant's amendments introduced new matter, as stated below.
3. Claims 23-43 are under examination.

Response to Arguments

4. The claim objections for claims 4-6 and 9-17 in the Office Action mailed June 16, 2006 are rendered moot in view of Applicant's cancellation of claims 1-22 in the amended claims filed August 16, 2006.
5. The obviousness-type double patenting rejection of claims 2-6, 8-12, 14 and 18-22 in the Office Action mailed June 16, 2006 are rendered moot in view of Applicant's cancellation of claims 1-22 in the amended claims filed August 16, 2006.
6. The 112, first paragraph rejection of claims 2-6 and 8-22 for lack of written description and lack of enablement in the Office Action mailed June 16, 2006 are rendered moot in view of Applicant's cancellation of claims 1-22 in the amended claims filed August 16, 2006.
7. The 35 USC 102 rejections of claims 2-6 and 8-12 in the Office Action mailed June 16, 2006 are rendered moot in view of Applicant's cancellation of claims 1-22 in the amended claims filed August 16, 2006.

Claim Objections

8. Claims 24-43 are objected to because of the following informalities: Claim 24 is drawn to the maize seed from the plant according to claim 23; however, claim 23 is drawn to a method for transferring a trait of interest and not to a maize plant. Claims 25-43 are included in the objection because they are dependent on claim 24.

The claim should amended to read: -- [The] A maize seed produced from the [plant] method according to claim 23. --

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph – Written Description

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 23-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are broadly drawn to a method for transferring any trait of interest into a maize plant wherein said trait is associated with one or more molecular markers.

The specification fails to provide an adequate written description with regards to the traits associated with the claimed markers in claim 23. Applicant claims a long list of markers, but the specification does not describe any of the markers in terms of any trait.

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Applicant further claims plants produced by the claimed method wherein said plants have specific traits such as tolerance to acid soils or resistance to aflatoxin, for example; however, the specification fails to provide any description of which, if any, of the long list of markers claimed confers such traits. The specification does not describe the claimed markers such that one skilled in the art would be able to determine which, if any, of the claimed markers is associated to a specific trait. Claims 24-43 are rejected because they are dependent upon claim 23.

Claims 28-31 and 33-43 are drawn to plants having specific characteristics; however, there does not appear to be literal support in the specification for plants with the claimed characteristics. Accordingly, the claims are directed to NEW MATTER.

Applicant argues, "[t]he applicant set forth the specific novel RFLPs in Table 2, pages 35-46, of the specification (see page 3, last paragraph of 'Remarks' filed August 16, 2006).

This is not persuasive. As stated above, the specification does not assign the specific trait associated with the claimed markers. The specification discloses, "[a] genetic marker is a polymorphism or variant allele that reveals the genetic locus or loci in an individual genotype that is associated with the phenotypic expression of a morphological or anatomical characteristic or a biochemical or physiological process" (see page 2, 3rd paragraph). The specification fails to reveal the genetic locus or loci in an individual genotype that is associated with the phenotypic expression of all the markers listed in the claimed method.

Applicant argues that one or more of the precise novel RFLPs, i.e. RFLPs not found in maize or the other *Zeas* as described on page 23 of the specification, are not shown to occur in four different teosinte-*Tripsacum* crosses (see page 3, last paragraph of 'Remarks' filed August 16, 2006).

This is not persuasive. The specification only provides a description for markers associated with resistance to, namely RFLP markers UMC103, BNL5.37, UMC28, UMC95, and/or their SSR corn rootworm markers bnlg2235, dupSSR23, phi123 and bnlg1714, respectively, and markers associated with aerenchyma, namely RFLP marker BNL8.32 and/or its respective SSR marker bnlg1805 (see page 29, last paragraph to page 30, lines 1-3). The specification fails to provide an association of the remaining claimed markers to any specific trait.

Applicant argues that one skilled in the art could easily test any plant to see if it contained one or more of the claimed markers (see page 4, lines 4-5 of 'Remarks' filed August 16, 2006).

This is not persuasive. The Examiner agrees that one skilled in the art could easily test any plant to see if it contained one or more of the claimed markers because Applicant states in the specification that the markers are publicly available (see page 21, 2nd paragraph). However, one skilled in the art would not know which traits are associated with the claimed markers. Applicant states that how traits are associated with molecular markers is described on page 24 of the specification; however, as stated above the specification only provides a description for markers associated with resistance to corn rootworm (which is not claimed), namely RFLP markers UMC103,

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BNL5.37, UMC28, UMC95, and/or their SSR markers bnlg2235, dupSSR23, phi123 and bnlg1714, respectively, and markers associated with aerenchyma, namely RFLP marker BNL8.32 and/or its respective SSR marker bnlg1805 (see page 29, last paragraph to page 30, lines 1-3).

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials". *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not description of that material". *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus". *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the failure of the specification to describe all the claimed markers with regards to the traits associated with said markers in conjunction with the lack of description regarding the claimed plants having the claimed characteristics listed in claims 28-31 and 33-43, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention. See the written description guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 4, 2001/ Notices: pp. 1099-1111.

See *University of Rochester v. G.D. Searle & Co., Inc.*, 68 USPQ2d 1424, 1433 (DC WNY 2003), which teaches that method claims are properly subjected to a written description rejection if the starting material required by that method is itself inadequately described.

The MPEP states "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002)".

See *Vas-Cath Inc. v. Mahurkar* 1991 (CA FC) 19 USPQ2d 1111, 1115, which teaches that the purpose of the written description is for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent;

and at the same time, of taking from the inventor the means of practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification.

Claim Rejections - 35 USC § 112, first paragraph – Enablement

11. Claims 23-43 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for transferring a trait of interest with markers associated with resistance to corn rootworm, namely RFLP markers UMC103, BNL5.37, UMC28, UMC95, and/or their SSR markers bnlg2235, dupSSR23, phi123 and bnlg1714, respectively, and markers associated with aerenchyma, namely RFLP marker BNL8.32 and/or its respective SSR marker bnlg1805, does not reasonably provide enablement for all the markers that are claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a method for transferring any trait of interest into a maize plant wherein said trait is associated with one or more molecular markers.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art,

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the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

The specification fails to provide any guidance regarding the traits associated with the claimed markers in claim 23 nor is there any guidance regarding the plants produced by the claimed method wherein said plants have specific traits (see claims 28-31 and 33-43); therefore it would require undue trial and error experimentation for one skilled in the art to make and use the claimed invention because one skilled in the art would not know which markers are associated with any particular trait. Claims 24-43 are rejected as well because they are dependent upon rejected claim 23.

The specification fails to provide any working examples of the claimed plants with respect to claims 28-31 and 33-43 and only provides working examples of plants having corn rootworm resistance (which is not claimed) and plants having roots that contain aerenchyma (see page 24, 3rd paragraph and page 27, 1st paragraph).

Applicant argues that the subject matter contained in the claims is described in the specification in such a way as to reasonably convey to one skilled in the art to make and use the claimed invention (see page 4, 2nd paragraph of 'Remarks' filed August 16, 2006).

This is not persuasive. Though the Examiner agrees that the specification does enable one skilled in the art to make and use the claimed invention using markers associated with resistance to corn rootworm (which is not claimed), namely RFLP markers UMC103, BNL5.37, UMC28, UMC95, and/or their SSR markers bnlg2235, dupSSR23, phi123 and bnlg1714, respectively, and markers associated with

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aerenchyma, namely RFLP marker BNL8.32 and/or its respective SSR marker bnlg1805 (see page 29, last paragraph to page 30, lines 1-3), the specification does not enable one skilled in the art to use the claimed invention with any of the remaining markers because these markers are not associated with any specific traits.

Applicant argues that it would not be necessary to screen the broad genus to possess the claimed novel restriction fragments for the specified molecular marker enzyme combinations because the method for making the cross pollinations to obtain hybrid plants that contain one or more of the RFLPs is described on pages 30-31 of the specification (see page 4, last line to page 5, lines 1-3 of 'Remarks' filed August 16, 2006).

This is not persuasive. The method for making the cross pollinations to obtain hybrid plants does not allow one skilled in the art to determine which, if any, of the claimed markers is associated with a particular trait.

Applicant argues that one skilled in the art could easily test any plant to see if it contained one or more of the claimed markers (see page 5, 1st paragraph of 'Remarks' filed August 16, 2006).

This is not persuasive. The Examiner agrees that one skilled in the art could easily test any plant to see if it contained one or more of the claimed markers because Applicant states in the specification that the markers are publicly available (see page 21, 2nd paragraph). However, one skilled in the art would not know which traits are associated with the claimed markers.

Applicant's arguments with regards to the specification being enabled for specific RFLPs associated with corn rootworm resistance and aerenchyma are persuasive (see page 5, 2nd and 3rd paragraphs of 'Remarks' filed August 16, 2006). The specification provides guidance and working examples regarding the claimed invention using RFLPs associated with corn rootworm resistance and aerenchyma.

Applicant has sent a copy of the deposit receipt for ATCC 75297 and argues that this verifies possession by the inventor and confirms seed of a teosinte-*Tripsacum* hybrid is publicly available (see page 6, 1st paragraph of 'Remarks' filed August 16, 2006).

Though Applicant is correct that a copy of the deposit receipt for ATCC 75297 verifies possession by the inventor and confirms seed of a teosinte-*Tripsacum* hybrid is publicly available, it does not enable the claimed invention because the claimed invention is a method for transferring any trait of interest into a maize plant wherein said trait is associated with one or more molecular markers and plants produced by said method. The deposit does not enable the method because the hybrid does not enable one skilled in the art to which markers are associated with specific traits. In addition, it does not enable the claimed plants (claims 24-43) because there is no evidence that the deposited line possesses all of the characteristics of these plants.

Claim Rejections - 35 USC § 102

12. Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Eubanks (U.S Patent 5,330,547). The rejection is repeated for reasons of record set

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forth in the previous Office Action mailed June 16, 2006 for claims 2-6 and 8-12 (see page 12).

The claims read on plants produced by crossing a *Tripsacum* plant with a teosinte plant, crossing the hybrid of said cross with maize and screening the plant's DNA for restriction fragments associated with a trait.

Eubanks discloses plants produced by crossing a *Tripsacum* plant with a teosinte plant, crossing the hybrid of said cross with maize (see column 7, lines 14-23 and columns 12-14, Tables 1-2). Though Eubanks does not further screen the plant's DNA as stated in step (f), the plant would inherently possess the claimed restriction fragments because the plant was produced by the same method as the claimed invention. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products. See *In re Best*, 195 USPQ 430, 433 (CCPA 1997), which teaches that where the prior art product seems to be identical to the claimed product, except that the prior art is silent as to a particularly claimed characteristic or property, then the burden shifts to Applicant to provide evidence that the prior art would neither anticipate nor render obvious the claimed invention.

Applicant argues that the subject matter contained in the claims and described in the specification could not possibly have been anticipated by the cited reference because the specification describes crosses with other *Tripsacum dactloides*

populations, some of which have a different ploidy level and different provenances (see page 7, 2nd paragraph of 'Remarks' filed August 16, 2006).

This is not persuasive. The cited reference discloses plants produced by crossing teosinte-*Tripsacum* hybrids with maize plants. These plants are produced by the same method as the instant invention and would inherently possess the claimed markers. Thus, it is irrelevant if other *Tripsacum dactloides* populations, some of which have a different ploidy level and different provenances are disclosed in the specification because the specification still discloses crossing teosinte-*Tripsacum* hybrids with maize plants.

New Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Eubanks (US Patent No. 5,750,828, May 12, 1998). The claims read on method for transferring any trait of interest into a maize plant wherein said trait is associated with one or more molecular markers and comprises the steps of crossing a *Tripsacum* plant with a teosinte plant, crossing the hybrid of said cross with maize and screening the plant's DNA for restriction fragments associated with a trait.

Eubanks discloses a method for transferring a trait of interest into a maize plant, namely corn rootworm resistance (see column 11, line 43 to column 14, line 48). Thus,

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the cited method would inherently produce plants with molecular markers associated to the trait as discussed above.

New Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eubanks (US Patent No. 5,330,547, July 19, 1994), in view of Gardiner et al (Genetics 134: 917-930, 1993). The claim reads on a method for transferring any trait of interest into a maize plant wherein said trait is associated with one or more molecular markers and plants produced by said method.

Eubanks teaches a method for transferring a trait of interest into a maize plant, namely corn rootworm resistance (see column 11, line 43 to column 14, line 48).

Eubanks does not teach using RFLP markers associated with specific traits.

Gardiner et al teach the use of RFLP markers associated with specific traits (see page 920, Table 2). One of ordinary skill in the art would understand that RFLP markers can be used to identify specific traits in marker-assisted selection.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to combine the teachings of Eubanks with those of Gardiner et al to produce method for transferring any trait of interest into a maize plant

wherein said trait is associated with one or more molecular markers and plants produced by said method.

One of ordinary skill in the art would have been motivated to combine these teachings because Gardiner et al teach, "[a] core marker set allows the minimal genome coverage necessary to map any quantitative or qualitative trait (see page 918, 1st column, 1st paragraph). In addition, Gardiner et al teach, "RFLP markers would be a useful starting point for any maize researcher wanting to map a particular trait" (see page 927, 2nd column, 2nd paragraph)

In addition, one of ordinary skill in the art would have reasonable expectation of success based on the success of Eubanks in producing a method for transferring a trait of interest into maize and the success of Gardiner et al associating RFLP markers with specific traits.

Conclusion

17. No claims are allowed.
18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith O. Robinson, Ph.D. whose telephone number is 571-272-2918. The examiner can normally be reached on Monday - Friday 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Keith O. Robinson, Ph.D.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



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